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(54) **END-OF-LIFE INDICATION SYSTEM FOR IMPLANTABLE PULSE GENERATOR**
LEBENSDAUERANZEIGESYSTEM FÜR EINPFLANZBAREN PULSGENERATOR
SYSTEME D'INDICATION DE FIN DE VIE D'UN GENERATEUR D'IMPULSIONS IMPLANTABLE

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Description

The present invention generally relates to battery end-of-life-indicators for implantable pulse generators- especially those suitable for neuromuscular stimulation.

Muscle-powered cardiac assist systems have been developed to aid patients with chronically and unacceptably low cardiac output, and who cannot have their cardiac output raised to acceptable levels by traditional treatments such as drug therapy. (See G.L. Anstadt & W.E. Britz, Jr., *Continued Studies in Prolonged Circulatory Support by Direct Mechanical Ventricular Assistance*, 14 Trans. Amer. Soc. Artif. Int. Organs 297 (1968)). U.S. Patent No. 4,813,952 issued to Khalafalla, teaches a cardiac assist system powered by surgically modified muscle tissue, such as the latissimus dorsi flap, using cardiomyoplasty techniques. Being fast twitch muscle tissue, the latissimus dorsi can be converted to slow twitch tissue for efficient long-term use by using the techniques taught in U.S. Patent No. 4,411,268 issued to Cox.

In a system using muscle wrapped about an ailing heart, an implantable pulse generator (IPG) senses contractions of a heart via one or more sensing leads, and stimulates the appropriate nerves of the muscle tissue (via stimulation leads) to cause the muscle tissue to contract in synchrony with the heart chamber of interest. As a result, the heart is made to contract more forcefully, raising the stroke volume, and hence cardiac output.

IPGs typically include end-of-life (EOL) indication circuitry for detecting and indicating an approaching depleted battery state. In prior art cardiac pacemakers, as disclosed e.g. in EP-A-0 431 437, a typical response to an EOL condition is to lower the pacing rate.

A special EOL indication signal can be transmitted transtelephonically from the IPG (whether cardiac, neuromuscular, etc.) when the patient is at a remote location. However, this requires specific special equipment at the receiver end to properly interpret the signal as an EOL signal. Thus, without the special equipment, a clinician interpreting the transtelephonic data would not know that an EOL condition is imminent, and would not then be able to advise the patient that the time for replacement of the IPG has arrived.

The following are objects of the present invention in view of the above.

A first object of the present invention is to provide a battery EOL indicator for an IPG which is functional via transtelephonic monitoring, and without the need for a special receiver/programmer.

A second object of the present invention is to provide a battery EOL indicator for an IPG which indicates an approaching EOL condition without the need to make reference to stimulation signal parameters.

A third object of the present invention is to provide an IPG with a battery EOL indicator in which current consumption is reduced upon an indication of an

approaching EOL condition, thus increasing the effective operation time of the unit.

A fourth object of the present invention is to provide a neuromuscular stimulation IPG capable of meeting all of the above objects.

There is provided in accordance with the present invention, a pacemaker system comprising:

an implantable pulse generator (IPG) comprising stimulation pulse generator means for generating stimulation pulse signals, battery end-of-life (EOL) monitoring means for detecting a parameter of a battery indicative of an approaching battery EOL condition in said battery, and stimulation pulse generator modifier means coupled to said stimulation pulse generator means for modifying said stimulation pulse signals generated by said stimulation pulse generator means; and characterized by a battery end-of-life (EOL) condition indicator means coupled to said EOL monitoring means and to said stimulation pulse generator modifier means; and wherein said IPG monitors cardiac stimulation signals and generates muscle stimulation bursts;

wherein upon the detection of an approaching battery EOL condition, said EOL condition indicator means activates said stimulation pulse generator modifier means to modify said muscle stimulation bursts and form discernible patterns indicating said approaching EOL condition, said discernible patterns corresponding to any discernible departure from a typical muscle stimulation burst signal

Details of preferred embodiments of the present invention will be revealed in the following description, given by way of example only, with reference to the attached drawings.

The various figures of the drawings are briefly described as follows:

Figure 1 is a first embodiment of a cardiac assist system capable of use with the present invention, wherein the skeletal muscle is wrapped about the myocardium

Figure 2 is an alternative embodiment of a cardiac assist system capable of use with the present invention, wherein the skeletal muscle is wrapped about the descending aorta.

Figure 3 is yet another alternative embodiment of a cardiac assist system capable of use with the present invention, wherein the skeletal muscle performs counterpulsation of the descending aorta.

Figure 4 is a block diagram of the IPG of the present invention.

Figure 5A is a sample electrocardiogram (ECG).

Figure 5B is an electrogram (EG) of muscle stimulation bursts corresponding to the ECG in Figure 5A, prior to the detection of an approaching EOL

condition.

Figure 5C is an EG of muscle stimulation bursts of a first embodiment of the present invention corresponding to the ECG in Figure 5A, after the detection of an approaching EOL condition.

Figure 5E is an EG of muscle stimulation bursts of a third embodiment of the present invention corresponding to the ECG in Figure 5A, after the detection of an approaching EOL condition.

The present invention employs a sensor to monitor cardiac electrical activity and cardiac demand in a skeletal muscle-powered cardiac assist system (CAS). A basic CAS may be configured in a variety of ways as described in the aforementioned patent to Khalafalla. Several of these configurations are discussed herein by way of illustration, and are not intended to limit the present invention.

Figure 1 is an embodiment of the present invention wherein skeletal muscle 22 is wrapped about a human heart 100. Skeletal muscle 22 is conditioned as a slow twitch muscle according to the aforementioned patent to Cox. An IPG 36 is coupled to a pacing lead 34 to produce a demand pacemaker. In addition, the IPG 36 stimulates skeletal muscle 22 to contract in synchrony with the heart 100. The simultaneous contraction of the skeletal muscle 22 provides assistance to the heart 100 to increase its systolic pressure in the descending aorta 102 and elsewhere in the circulatory system.

According to the present invention, the IPG 36 employs an activity sensor 104 to, in addition to sensing cardiac activity via the pacing lead 34, sense and output indicia of the patient's activity, and hence cardiac demand.

Figure 2 is an alternative embodiment of the CAS in Figure 1. In this embodiment, skeletal muscle 22 is wrapped about an artificial chamber 20, which chamber is inserted in series with the descending aorta 102. Unlike the embodiment in Figure 1, the IPG 36 stimulates the skeletal muscle 22 to contract following evacuation of the heart 100, which is accomplished by the insertion of a delay between a paced or sensed beat of the heart 100 and the stimulation of the skeletal muscle 22 as discussed *infra*.

Figure 3 is another alternative embodiment of the CAS in Figure 1 wherein an artificial chamber 20 is coupled external to the descending aorta 102. In this configuration the skeletal muscle 22 is stimulated to counter-pulse the heart 100, which raises its diastolic pressure thereby increasing its perfusion. This is accomplished by the generation of sufficient delay by the IPG 36, between and sensed or paced contraction of the heart 100 and stimulation of the skeletal muscle 22 to cause the desired counter-pulsation.

Figure 4 is a schematic block diagram of the IPG of the present invention. It includes a demand pacing generator 154 as is known in the art. In operation, the electrical activity of the patient's heart is monitored via the

pacing lead 34. A sense amplifier 156 detects any naturally occurring heart depolarization (representing a contraction), and notifies the pacing generator 154. If the natural depolarization is sensed within an allotted time, the output of the pacing generator 154 is inhibited. However, if the pacing generator 154 determines that sufficient time has elapsed since the previous depolarization, it generates a pacing pulse to the heart via the pacing lead 34 to artificially stimulate the heart 100 to contraction.

A stimulation generator 166 generates a burst of pulses in a manner known in the art to cause contraction of the skeletal muscle 22 in the proper timing relation to the contraction of the heart 100. Accordingly, an OR-gate 160 produces an output whenever the sense amplifier 156 senses a naturally occurring contraction, or whenever the pacing generator 154 generates a pacing pulse. The output of the OR-gate 160 enables timing logic 162, which generates a desired amount of delay. The delay is nearly zero for the embodiment of Figure 1 because maximum assistance to the heart 100 is provided when the skeletal muscle 22 contracts in synchrony with the heart.

The embodiment of Figure 2 requires a longer delay, on the order of one-half the cardiac cycle (i.e., the R-to-R interval). The embodiment of Figure 3 requires yet a longer delay, being somewhat greater than one-half the cardiac cycle. This is necessary because that embodiment is intended to increase diastolic pressure in the aorta.

The output of the timing logic 162 is a timing pulse timed according to the specific embodiment (e.g., Figures 1, 2 or 3). The timing pulse is supplied to a duty cycle timing circuit 164, which is a variable digital counter producing an output corresponding to a variable number of pulses received from the timing logic 162. The normal output of the duty cycle timing circuit 164 is one pulse for each pulse received from the timing logic 162, corresponding to one-for-one stimulation of skeletal muscle rate compared to the cardiac rate. It should be understood that a lower rate is possible.

Overall cardiac rate is determined by an integrator 158, which receives input signals from both the sense amplifier 156 and the pacing generator 154, representing naturally occurring contractions and paced contractions, respectively. The integrator 158 produces an average current heart rate, which is used by the duty cycle timing circuit 164 to adjust its variable rate counter.

The output from the duty cycle timing circuit 164 controls the generation, *vel non*, of muscle stimulation pulses from a stimulation generator 166 via a stimulation lead 32. The pulses from the stimulation generator 166 typically form a series of bursts needed for neuromuscular stimulation.

Activity signals from the activity sensor 104 are processed by a signal processing circuit 152 to filter out noise and other unwanted components. The processed

activity signals modulate the duty cycle timing circuit 164 and the stimulation generator 166, so as to change the burst rate and number of burst pulses in accordance with anticipated cardiac demand.

In accordance with the present invention, an EOL detector 180 detects an approaching EOL condition of the IPG batteries (not shown), in any one of a number of ways well known in the art, such as disclosed in U.S. Patent 3,841,336 issued to Daynard, and 3,882,322 issued to Gobeli, to name just two. The EOL detector 180 sends an EOL signal to the pacing generator 154, which according to a pre-programmed protocol can cause the number of pulses in a burst to be reduced, cause the synchronization ratio (number of cardiac contractions compared to the number of powering muscle contractions) to increase, or a combination of the two.

Figure 5A is an ECG of a muscle-assisted heart, absent the corresponding muscle stimulation burst signals. In actuality, the resulting ECG of a CAS using cardiomyoplasty, for example, would be expected to contain indicia of the muscle stimulation burst signals. As such, Figures 5B-5E are merely convenient representations of possible muscle stimulation burst signals which may occur at the same time as the partial ECG in Figure 5A. Figure 5B is a representation of a standard muscle stimulation burst signal pattern for the powering muscle tissue before the battery voltage V_1 .

The ECG is transtelephonically transmitted from the patient's remote location to a clinician's receiver and display monitor by a device (not shown) external to the IPG in the preferred embodiment. In an alternative embodiment, a telemetered signal generated from within the IPG could transmit the ECG when the muscle pacing artifact cannot be seen very well, for example.

In response to an EOL signal from the EOL detector 180 (i.e., $V_B \leq V_1$), the IPG 36 changes the muscle stimulation burst signals from the standard pattern shown in Figure 5B to any of the patterns shown in Figures 5C-5E (all corresponding in time to the ECG in Figure 5A), or combinations thereof. In Figure 5C the muscle stimulation burst signals have a reduced number of pulses in the burst. In that example the number of pulses is halved by reducing them from four in Figure 5B to two. A clinician viewing a telephonically transmitted ECG would expect the muscle stimulation burst signal to appear as shown in Figure 5B. Therefore, any discernible departure from a typical muscle stimulation burst signal is an indication of the EOL condition, and is readily apparent to a clinician viewing the ECG alone, without the need for special circuitry. So, the drop in the number of burst pulses in Figure 5C is a clear indication that the EOL condition is approaching.

As an alternative to the response represented by Figure 5C, the synchronization ratio can be increased. Thus, in Figure 5D the number of burst pulses remains standard (the same as in Figure 5B), but the synchronization ratio changes from 1-to-1 to 2-to-1. This would be another form of an EOL indication to the clinician.

In yet another alternative to the EOL indication pattern, the burst pulses can alternate between two different numbers on alternate cycles. Thus, in Figure 5E, the number of burst pulses alternates between four and two.

With further battery depletion, the number of burst pulses can be further reduced, and the synchronization ratio can be further raised, and the amount of change in these parameters can be made to be proportional to the amount of battery depletion.

In addition to providing a simple EOL indicator, the present invention also results in reduced battery current consumption, thus prolonging the before-replacement useful battery life.

Variations and modifications to the present invention may be possible given the above disclosure. However, all such variations and modifications are intended to be within the scope of the invention defined by the claims. For example, the present invention is intended for use with therapeutic pulse generators in general, and not necessarily limited to muscle stimulators.

Additional changes to the stimulation bursts, and hence the ECG, could be used to indicate further battery voltage depletion after the EOL condition is reached. For example, the number of pulses in the burst is not only an indication of the EOL condition (when less than the full number are included in each burst), but is also proportional to the battery voltage, with further reductions in pulse number indicating further reduction in the battery voltage. The synchronization ratio can be varied in a similar (but opposite in the preferred embodiment) manner.

The present invention could also be manually triggered by a magnet to transmit an ECG which indicates the battery voltage by the presence, *vel non*, and magnitude of the previously-mentioned muscle pacing artifact pattern changes.

Claims

1. A pacemaker system comprising:

an implantable pulse generator (IPG) (36) comprising stimulation pulse generator means (166) for generating stimulation pulse signals, battery end-of-life (EOL) monitoring means (180) for detecting a parameter of a battery indicative of an approaching battery EOL condition in said battery, and stimulation pulse generator modifier means (154) coupled to said stimulation pulse generator means (166) for modifying said stimulation pulse signals generated by said stimulation pulse generator means; and characterized by a battery end-of-life (EOL) condition indicator means coupled to said EOL monitoring means (180) and to said stimulation pulse generator modifier means (166); and wherein said IPG

(36) monitors cardiac stimulation signals and generates muscle stimulation bursts;

wherein upon the detection of an approaching battery EOL condition, said EOL condition indicator means activates said stimulation pulse generator modifier means (166) to modify said muscle stimulation bursts and form discernible patterns indicating said approaching EOL condition, said discernible patterns corresponding to any discernible departure from a typical muscle stimulation burst signal.

2. The pacemaker system in claim 1, wherein said stimulation pulse generator modifier means (154) modifies the number of pulses in said muscle stimulation bursts when activated.
3. The pacemaker system in claim 2 wherein said stimulation pulse generator modifier means (154) is adapted to further modify the number of pulses in said muscle stimulation bursts when the voltage of said battery is reduced beyond an EOL condition.
4. The pacemaker system in claim 1 wherein said stimulation pulse generator modifier means (154) modifies a synchronization ratio between said cardiac stimulation signals and said muscle stimulation bursts.
5. The pacemaker system in claim 4 wherein said stimulation pulse generator modifier means (154) is adapted to further modify said synchronization ratio when the voltage of said battery is reduced beyond and EOL condition.
6. The pacemaker system in any preceding claim further comprising manual triggering means for manually triggering the operation of said battery EOL condition indicator.
7. The pacemaker system in claim 6 wherein said manual triggering means is magnetic.

Patentansprüche

1. Schrittmachersystem mit

einem implantierbaren Impulsgenerator (IPG) (36) mit einer Stimulierimpuls-Generatoreinrichtung (166) zum Erzeugen von Stimulierimpulssignalen, einer Batterie-Lebensdauerende-(EOL)-Überwachungseinrichtung (180) zum Erfassen eines nahenden Batterie-EOL-Zustand anzeigenden Batterieparameters und einer mit der Stimulierimpuls-Generatoreinrichtung (166) gekoppelten Stimulierimpuls-generator-Modifiziereinrichtung (154) zum Modifizieren der von der Stimulierimpuls-

Generatoreinrichtung erzeugten Stimulierimpulssignale,

wobei bei Erfassen eines nahenden Batterie-EOL-Zustandes die EOL-Zustandsanzeigeeinrichtung die Stimulierimpuls-generator-Modifiziereinrichtung (166) aktiviert, so daß diese die Muskelstimulierstöße modifiziert und der Form nach unterscheidbare Muster erzeugt, die den nahenden EOL-Zustand anzeigen, wobei die unterscheidbaren Muster einer beliebigen unterscheidbaren Abweichung von einem typischen Muskelstimulier-Stoßsignal entsprechen,

gekennzeichnet durch eine mit der EOL-Überwachungseinrichtung (180) und der Stimulierimpuls-generator-Modifiziereinrichtung (166) gekoppelte Batterie-EOL-Zustandsanzeigeeinrichtung, wobei der IPG (36) Herzstimuliersignale überwacht und Muskelstimulierstöße erzeugt.

2. Schrittmachersystem nach Anspruch 1, wobei die Stimulierimpuls-generator-Modifiziereinrichtung (154) im aktivierten Zustand die Anzahl der Impulse in den Muskelstimulierstößen modifiziert.
3. Schrittmachersystem nach Anspruch 2, wobei die Stimulierimpuls-generator-Modifiziereinrichtung (154) so ausgelegt ist, daß sie die Anzahl der Impulse in den Muskelstimulierstößen modifiziert, wenn die Batteriespannung unter einen EOL-Zustand absinkt.
4. Schrittmachersystem nach Anspruch 1, wobei die Stimulierimpuls-generator-Modifiziereinrichtung (154) ein Synchronisationsverhältnis zwischen den Herzstimulierimpulsen und den Muskelstimulierstößen modifiziert.
5. Schrittmachersystem nach Anspruch 4, wobei die Stimulierimpuls-generator-Modifiziereinrichtung (154) so ausgelegt ist, daß sie das Synchronisationsverhältnis modifiziert, wenn die Batteriespannung unter einen EOL-Zustand absinkt.
6. Schrittmachersystem nach einem der vorhergehenden Ansprüche mit einer Handauslöseeinrichtung zum manuellen Auslösen der Funktion des Batterie-EOL-Zustandsanzeigeeinrichtung.
7. Schrittmachersystem nach Anspruch 6, wobei die Handauslöseeinrichtung magnetisch ist.

Revendications

1. Système de stimulateur comprenant :

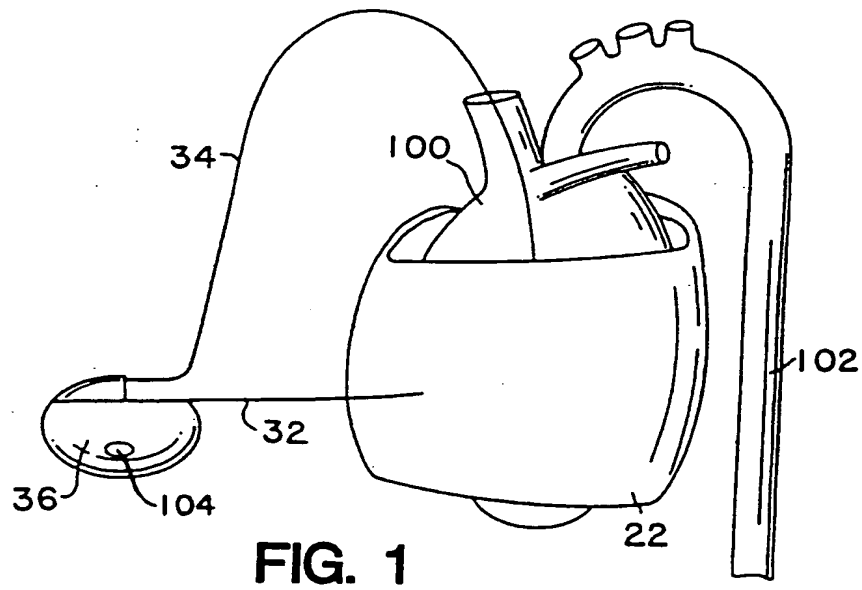
un générateur d'impulsions implantable (IPG)

(36) comprenant des moyens de production d'impulsions de stimulation (166) pour produire des signaux d'impulsion de stimulation, des moyens de surveillance (180) de fin de vie (EOL) de pile afin de détecter un paramètre d'une pile révélateur dans ladite pile de l'approche d'une condition d'EOL de la pile, et des moyens de modification du générateur d'impulsions de stimulation (154) couplés auxdits moyens de production d'impulsions de stimulation (166) pour modifier lesdits signaux d'impulsion de stimulation produits par lesdits moyens de production d'impulsions de stimulation; et caractérisé par des moyens d'indication de la condition de fin de vie (EOL) de la pile reliés auxdits moyens de surveillance d'EOL (180) et auxdits moyens de modification du générateur d'impulsions de stimulation (166); et dans lequel ledit IPG (36) surveille les signaux de stimulation cardiaque et produit des salves de stimulation du muscle; dans lequel lors de la détection de l'approche d'une condition d'EOL de la pile, les moyens d'indication de la condition d'EOL activent les moyens de modification du générateur d'impulsions de stimulation (166) pour modifier lesdites salves de stimulation du muscle et former des motifs perceptibles révélateurs de ladite approche de la condition d'EOL, lesdits motifs perceptibles correspondant à tout écart perceptible par rapport à un signal de salve de stimulation du muscle classique.

2. Système de stimulateur selon la revendication 1, caractérisé en ce que les moyens de modification du générateur d'impulsions de stimulation (154) modifient le nombre d'impulsions dans lesdites salves de stimulation du muscle une fois activé.
3. Système de stimulateur selon la revendication 2, caractérisé en ce que lesdits moyens de modification du générateur d'impulsions de stimulation (154) sont faits pour, en outre, modifier le nombre d'impulsions dans lesdites salves de stimulation du muscle quand la tension de ladite pile est abaissée au-delà d'une condition d'EOL.
4. Système de stimulateur selon la revendication 1, caractérisé en ce que lesdits moyens de modification du générateur d'impulsions de stimulation (154) modifient un rapport de synchronisation entre lesdits signaux de stimulation cardiaque et lesdites salves de stimulation du muscle.
5. Système de stimulateur selon la revendication 4, caractérisé en ce que lesdits moyens de modification du générateur d'impulsions de stimulation (154) est fait pour modifier également ledit rapport

de synchronisation quand la tension de ladite pile est abaissée au-delà d'une condition d'EOL.

6. Système de stimulateur selon l'une quelconque des revendications précédentes, comprenant en outre des moyens de déclenchement manuels pour déclencher manuellement le fonctionnement dudit indicateur de la condition d'EOL de la pile.
7. Système de stimulateur selon la revendication 6, caractérisé en ce que lesdits moyens de déclenchement manuels sont magnétiques.



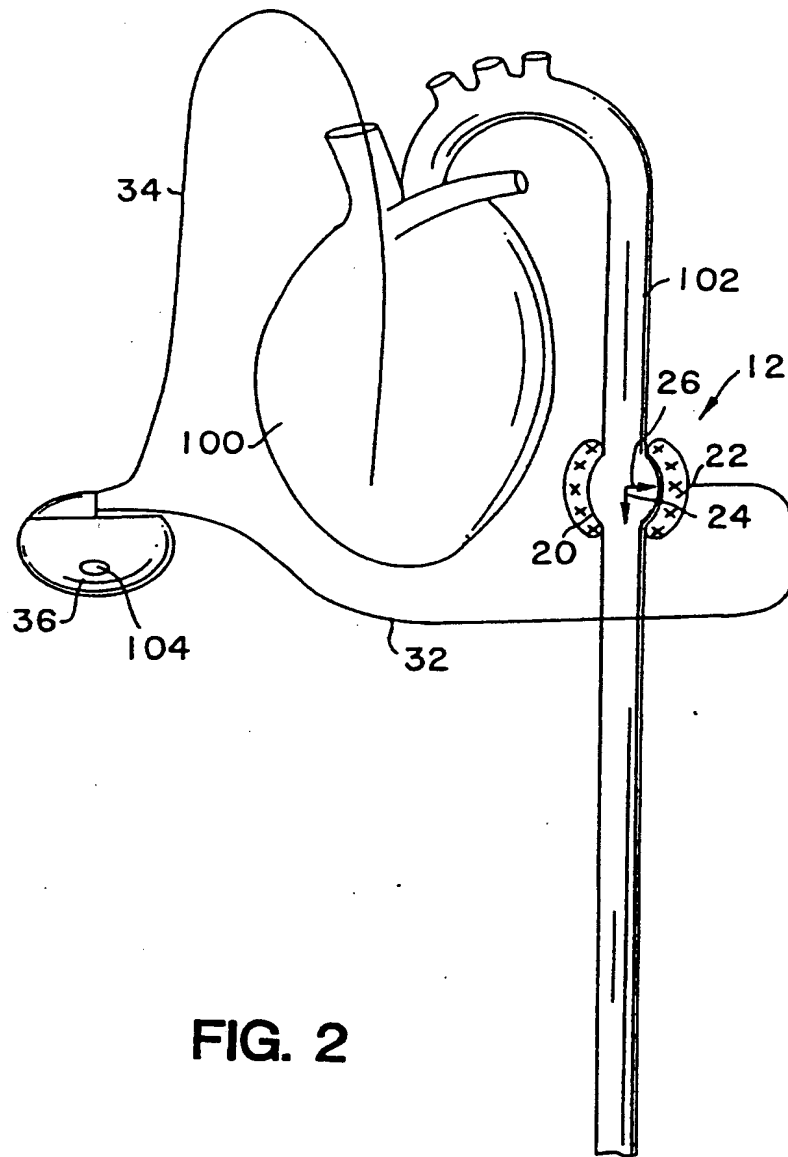


FIG. 2

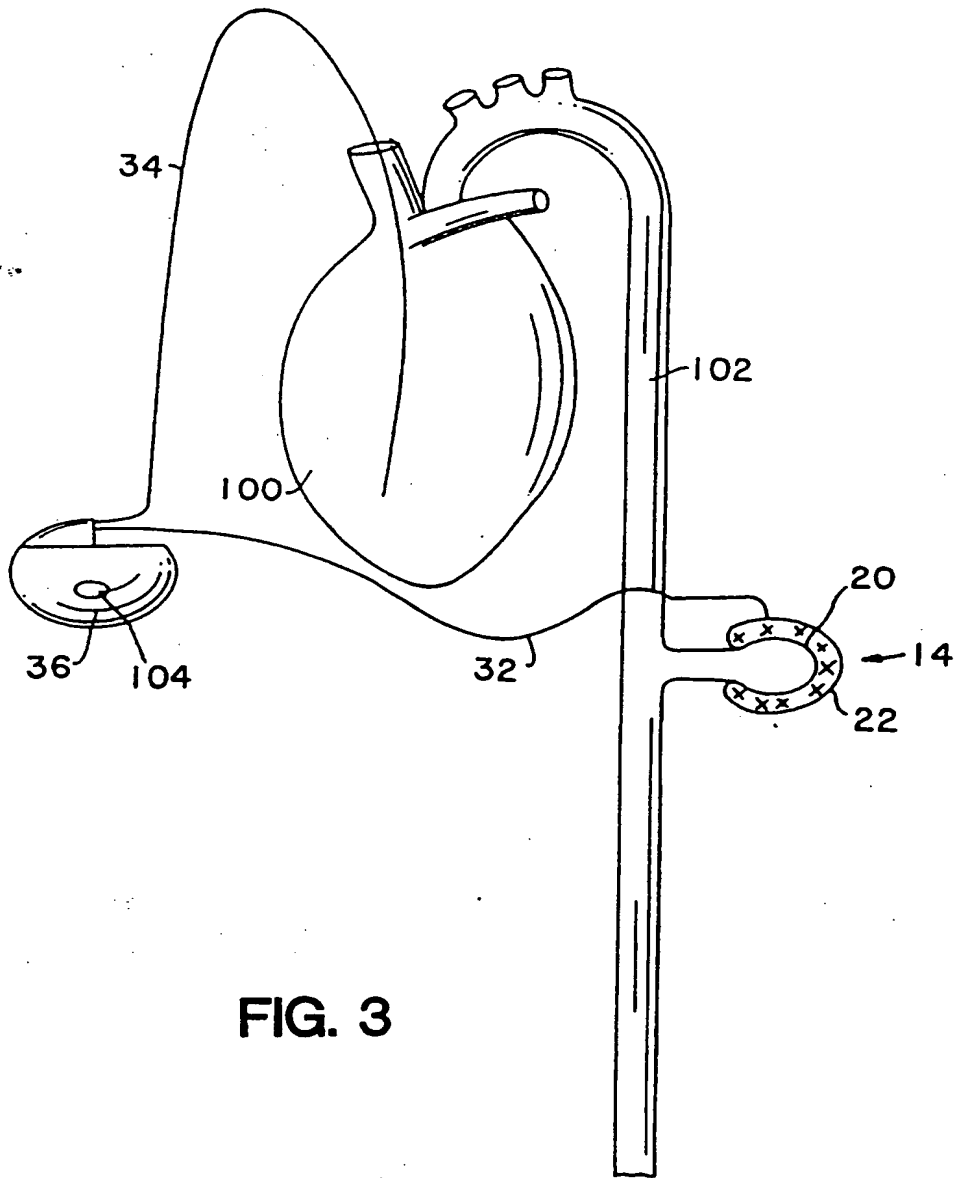
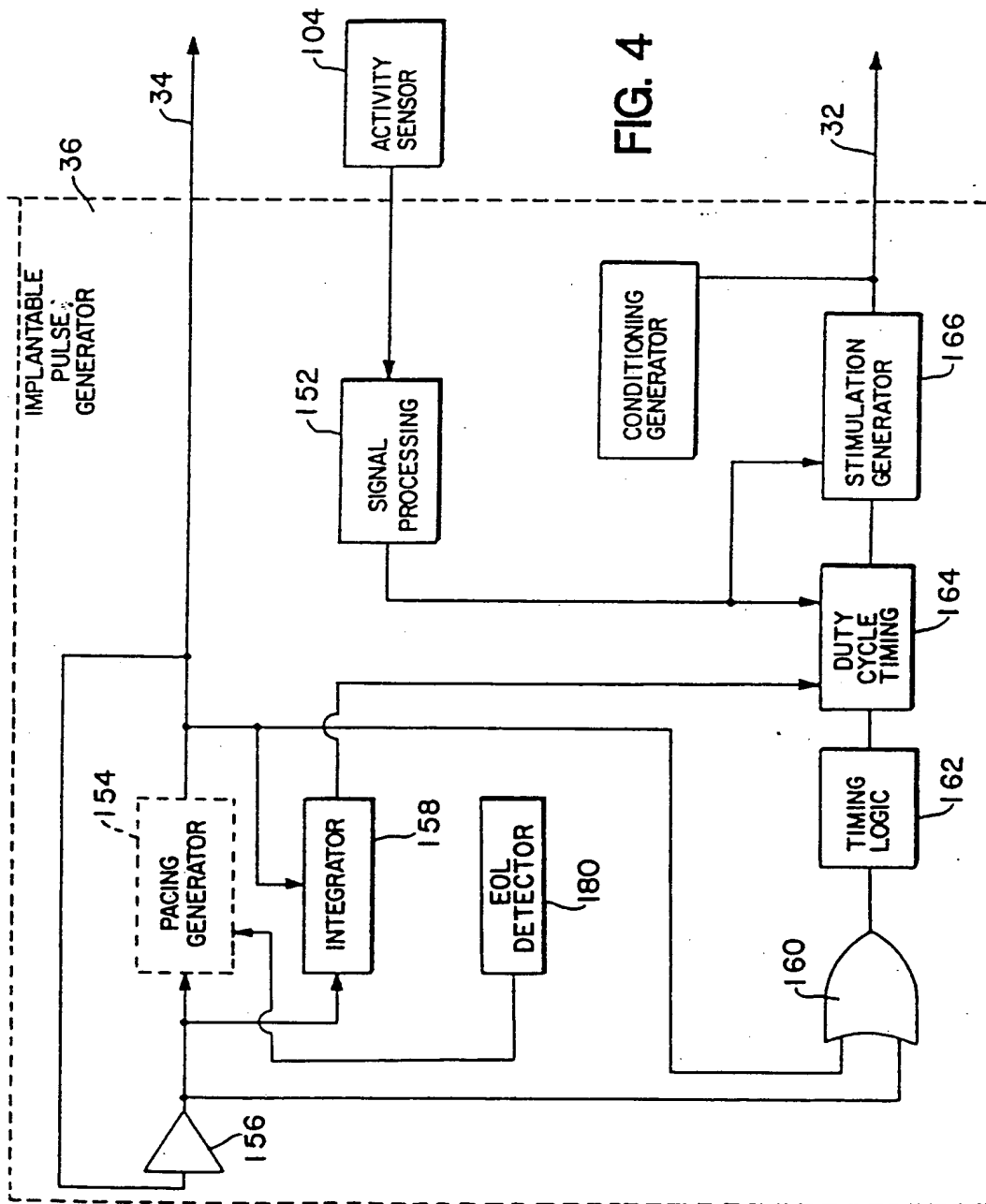


FIG. 3



ECG  FIG.5A

$V_B > V_I$
MUSCLE OUTPUT  FIG.5B

1) $V_B \leq V_I$
MUSCLE OUTPUT  FIG.5C

2) $V_B \leq V_I$
 FIG.5D

3) $V_B \leq V_I$
 FIG.5E